REMARKS

Applicants have carefully reviewed and considered the Final Office Action dated May 6, 2005, and the references cited therewith. In response, no claims are amended, no claims are added, and no claims are cancelled; as a result, claims 1-14 are now pending in this application.

Applicants hereby respectfully request further examination and reconsideration of the application in view of the following remarks.

§103 Rejection of the Claims

Claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. 4,743,229) in view of Kanno (U.S. 4,629,455). Applicants respectfully traverse this rejection on at least two grounds.

First, the cited references, neither alone nor in combination, teach or suggest all the limitations of the claims. According to M.P.E.P § 2142, the prior art reference (or references) must teach or suggest *all* of the claim limitations. (Emphasis added). Validity is determined on the basis of the subject matter of a claim as a whole. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 227 U.S.P.Q. 337 (Fed. Cir. 1985), *remanded*, 475 U.S. 809, 229 U.S.P.Q. 478 (1986), *on remand*, 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). "[I]t is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties, and the problem it solves." *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q.2d 1959 (Fed. Cir. 1988). The Patent and Trademark Office (PTO) is "obligated to consider all the evidence of the properties of the claimed invention as a whole, compared with those of the prior art." *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897 (Fed. Cir. 1990)(in banc), *cert. denied*, 500 U.S. 904 (1991).

Second, there is no suggestion to modify or combine the cited references. According to *In re Lee*, "there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002)(citing *In re Fine*), *see also ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)(holding "[o]bviousness cannot be

established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination"). As further stated by *In re Lee*, the "factual question of motivation is material to patentability, and *[can] not be resolved on subjective belief and unknown authority*." *In re Lee*, 61 U.S.P.Q.2d 1430 (emphasis added). "We do not 'pick and choose among the individual elements of assorted prior art references to recreate the claimed invention,' but rather, we look for 'some teaching or suggestion in the references to support their use in the particular claimed combination.'" *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991).

The fact that a prior art device could be modified so as to produce the claimed device is not a basis for an obviousness rejection unless the prior art suggested the desirability of such a modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). A PTO rejection is improper when there is nothing in the cited prior art references, either singly or in combination, to suggest the desirability of the claimed subject matter. *In re Deminski*, 796 F.2d 436, 230 U.S.P.Q. 313 (Fed. Cir. 1986). That the construction in a particular prior art reference would have resulted in the claimed combination had it followed the "common practice" of attaching certain parts does not show obviousness at the time of the invention but rather reflects improper hindsight analysis and reading into the art of the applicant's own teachings. *Id.*

The cited references, neither alone nor in combination, teach or suggest all the limitations of the claims:

Claims 1-14:

The Final Office Action (FOA) asserts that "Chu teaches all of the limitations of the claims except for explicitly reciting [a] locking ring being rotatably coupled with the male end portion." (FOA, pp. 2). The FOA further asserts that "Kanno teaches a rotatably coupled locking ring mounted on a medical instrument." (*Id.*). Contrary to the position taken by the FOA, the Applicants cannot find in Chu (nor Kanno)

> "a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip, . . . a second

> syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring, . . . the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein; wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement,"

as recited in Applicants' claim 1. Unlike the claimed invention, Chu recites a separate connector means 50 which is used to connect a first syringe 12 to a second syringe 14. (Chu, col. 4, lns. 45-52). FIG. 2 clearly illustrates that the connection means 50 is an element not integrated with either the first syringe 12 or the second syringe 14 (i.e., an element separate from both the first syringe 12 and the second syringe 14). (*See* Chu, FIG. 2).

The FOA implicitly recognizes that, unlike Chu, the Applicants claimed invention does not require a separate connection element to be positioned between the syringes to establish a connection therebetween. To this end, however, the FOA takes the position that "Applicant recites a coupling syringe system *comprising*, making suitable the existence and use of the additional connection element." (FOA, pp. 3)(emphasis in original). The Applicants assert that the foregoing position fails in establishing a *prima facie* case of obviousness on at least two grounds. First, although the open transitional phrase "comprising" is used allowing for the inclusion of a separate connection element, the limitations of Applicants' claim 1 as a whole remain unmet (e.g., "a first syringe *including* . . . a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip", "a second syringe *including* . . . a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring", "wherein the locking ring couples the first syringe to the second syringe when the *tip of the male end portion is disposed within the female end portion*").

Second, the addition of a separate connection element to be positioned between the syringes to establish a connection is not in concert with the Applicants' invention as a whole, as required by *In re Wright*. As one example, the Applicants' invention provides a solution to a problem of mixing systems including two syringes with an independent coupling means (i.e., a

system similar to Chu). (Applicants' Application, pp. 2, lns. 1-9; pp. 4, lns. 1-9; pp. 6, lns. 6-15). Specifically, the Applicants state in their application:

> "[t]he present invention provides a syringe system wherein components of a composition can be easily mixed by the end user without losing a significant amount of mixed composition during the mixing process and wherein the mixed composition can be easily and rapidly administered to a patient. The syringe system has a relatively few number of interconnecting parts, to minimize human error and to minimize sample loss. Additionally, the syringe system effectively mixes the contents located therein without sample loss, such that it can be approved by the FDA when used with drugs that must be administered in a known, discrete and precise amount (e.g., leuprolide acetate)."

(*Id.*, pp. 4, lns. 12-20). Moreover, the Applicants state that "[t]he use of the coupling syringe system of the invention does not result in a plug flow of contents . . . [and] can conveniently be disassembled and a needle can conveniently be attached to the syringe which includes a male end portion and a locking ring." (*Id.*, pp. 6, lns. 12-15).

As another example, the Applicants' invention does not require a separate connection element to be positioned between the syringes to establish a connection. Specifically, the Applicants' application states that "syringe system 1 includes a first syringe 13 and a second syringe 14[,] . . . first syringe 13 includes a barrel 2 . . . ha[ving] a distal end 3 . . . [which] is characterized with a tip 8[,] . . . tip 8 is [ ] provided with a male end portion 10 wherein the male end portion 10 is provided with a locking ring 11[;] . . . second syringe 14 ha[s] a barrel 18 . . . ha[ving] a distal end 19 . . . [which] is characterized with a tip 25[,] . . . tip 25 [ ] is provided with a female end portion 27 wherein the female end portion 27 is configured to detachably connect to the locking ring 11." (*Id.*, pp. 6, lns. 16-28; pp. 7, lns. 7-21).

The FOA further takes the position that it "may rely on the connection piece in combination with the first syringe to constitute a male/female end of the connection piece combination for connection to the second syringe when applying the broadest possible interpretation of the claim." (FOA, pp. 3). The Applicants assert that such position also fails to make out (i.e., establish) a *prima facie* case of obviousness on at least two grounds. First, as applied to Chu, "the connection piece [50] in combination with the first syringe [12] . . . for connection to the second syringe [14]" does not meet the limitations of Applicants' claim 1 as a whole. As one example, the connection piece [50]/first syringe [12] combination does not meet

the limitation "the first syringe . . . including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip," as recited in Applicants' claim 1. As another example, the connection piece [50]/first syringe [12] combination does not the limitation "the second syringe . . . including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring," as further recited in Applicants' claim 1.

Second, "the connection piece [50] in combination with the first syringe [12] . . . for connection to the second syringe [14]" is not in concert with the Applicants' invention as a whole, as required by *In re Wright*. As one example, the direct detachable connection between the first and second syringes of the Applicants' claimed invention importantly allows for the forming of a mixed composition without "result[ing] in a significant loss of the composition." (Applicants' Application, pp. 6, lns. 7-8). This property/characteristic is especially important when mixing drug compositions, such as leuprolide acetate, that are closely regulated by the Food and Drug Administration (FDA). Even very small amounts of leakage of leuprolide acetate would be troubling for at least two reasons. First, any leakage would result in waste of an expensive drug. Second (and more importantly), because leuprolide acetate is a potent drug that must be administered in a narrow dosage range, the FDA would not approve a device for its mixing or delivery that resulted in a delivery of an uncertain amount of the drug. Other drugs that the Applicants' direct coupling syringe system is intended to mix may also have the characteristics of being expensive and/or having a dosage closely regulated by the FDA. To be used with these drugs, the coupling syringe system must not result in a significant loss/leak.

Unlike the Applicants' invention, the connection piece [50]/first syringe [12] combination suggested by the FOA results in a fluid pathway extending from at least end ridge 52 to end ridge 54 (*see* Chu, FIGS. 1-3), the contents of which must be aspirated out of the pathway or they will be lost. As discussed above, the plug flow of contents is one of the problems that the Applicants' claimed invention was made to solve. Notably, the plug flow of contents does not appear to be a concern in Chu. As one example, Chu states that "[a] preferred ratio of collagen dispersion to mineral [(i.e., the two compositions to be mixed in Chu)] is about

1:1 by weight, *but ratios as high as about 4:1 are acceptable.*" (Chu, col. 5, lns. 23-25)(emphasis added). In other words, the necessity for precision as to the ratio of the compositions to be mixed is lacking in Chu.

Claims 2-14 are dependent on claim 1 and are patentable over Chu in view of Kanno for the reasons argued above, plus the elements in such claims.

There is no suggestion to modify or combine the cited references:

Claims 1-14:

Applicants cannot find any motivation, suggestion, or teaching to combine the teachings of Chu with the teachings of Kanno to make the specific combination that was made by Applicants, as required by *In re Lee*. Specifically, Applicants cannot find in Chu any motivation, suggestion, or teaching to combine the teachings therein with the teachings of Kanno for the purpose of creating "a first syringe including . . . a first syringe tip with a male end portion wherein the male end portion has a locking ring . . . wherein the locking ring couples the first syringe to [a] second syringe when [a] tip of the male end portion is disposed within [a] female end portion, forming a fluid tight engagement," as recited in Applicants' claim 1.

The FOA acknowledges that Chu provides no such motivation, suggestion, or teaching, but states that "[i]t would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the connecting structure of Chu with the connecting member as taught by Kanno for the well known purpose of providing a male and female connection alternative that can be joined firmly with high reliability." (FOA, pp. 2). Applicants submit that this is an unsupported assertion, as prohibited by *In re Lee*. It is respectfully submitted that the above-identified assertion amounts to a form of Official Notice, which is timely traversed herein under M.P.E.P. § 2144.03, and if the Examiner is aware of a reference providing support for the assertion, citation of such reference is respectfully requested. If a reference cannot be provided, Applicants submit the assertion is formed on the personal knowledge of the Examiner, and Applicants request that an affidavit is provided, as required by 37 C.F.R. § 1.104(d), or removal of this 35 U.S.C. § 103 basis of rejection.

Moreover, Applicants submit that Chu recites a first adapter 42 located at an end 18 of a first syringe 12 and a second adapter 44 located at an end 24 of a second syringe 14. (Chu, col. 4, lns. 45-48). Chu states that "these adapters are preferably male Luer connectors which may be provided with internal threads." (*Id.*, col. 4, lns. 48-50). "The adapters are joined by connector means 50 which is preferably a female Luer connector. End ridges 52 and 54 of the female Luer connector are adapted to fit within the threads 46 and 48 of the male Luer connector." (*Id.*, col. 4, lns. 50-54). Chu further recites an alternative embodiment in which "threads 46 and 48 may be replaced by an internal groove which provides a 'snap'-type connection with female Luer connector 50." (*Id.*, col. 4, lns. 55-57). In sum, Chu recites two connection schemes that may join (in fluid communication) a first device to a second device and makes no mention of a need for additional connection alternatives. Accordingly, one of ordinary skill in the art would have had no reason to consider additional connection alternatives to make a connection between two devices, such as a first syringe and a second syringe or discharge assembly. Rather, one of ordinary skill would have appreciated the desirability of the Applicants' claimed invention, including a male/female connection utilizing a syringe integrated locking ring to join a first syringe to a second syringe or discharge assembly, only upon access to the Applicants' disclosure which is impermissible. For this reason, Applicants respectfully request withdrawal of the 35 U.S.C. § 103 basis of rejection of claims 1-14.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (612) 359-3261 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD L. DUNN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3261

Date 9/3/05

By _____
Gary J. Speier
Reg. No. 45,458

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 31st day of August, 2005.

Dawn M. Poole

Name

Dawn M. Poole

Signature